Cont A5

136. The composition of claim 134, wherein said composition further comprises a pharmaceutically acceptable carrier.--

Please refer to the attachment for the marked-up versions of the amended specification and claims, pursuant to 37 C.F.R. § 1.121.

REMARKS

Claims 1 through 52 are pending. Claims 53 through 116 have been withdrawn from further consideration under 37 C.F.R. § 1.142(b). Paper No. 5, at page 2. The Examiner made the restriction requirement, which Applicants timely traversed, final. *Id.* Applicants reserve the right to file one or more divisional applications directed to the subject matter of the non-elected claims.

Claims 1, 19, 36 and 37 are amended. The specification and original claims support the amendments to the pending claims. Claims 117 through 136 are added and support is found throughout the specification, e.g., at pages 4 through 9. It is submitted that the amendments and the new claims introduce no new matter and entry of the same is respectfully requested.

By these amendments and new claims, the Applicants do not acquiesce to the propriety of any of the Examiner's rejections and do not disclaim any subject matter to which the Applicants are entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 56 U.S.P.Q.2d 1865 (Fed. Cir. 2000), *cert. granted*, 121 S. Ct. 2519 (U.S. June 18, 2001) (No. 00-1543).

Objection under 37 C.F.R. § 1.75(c)

The Examiner rejected claims 2-13, 39-40, and 42-52, asserting that the claims were in "improper dependent form for failing to further limit the subject matter of a previous claim." Paper No. 5 at page 2. Applicants respectfully traverse.

Contrary to the Examiner's assertion, claims 2-13, 39-40, and 42-45 are in compliance with 37 C.F.R. § 1.75(c) in that they are in proper dependent form. However, Applicants have amended independent claims 1 and 37, from which claims 2-13, 39-40, and 42-52 depend, to recite in the body of the claim "wherein said composition is administerable to a patient or person," thus obviating the present objection. Hence, Applicants respectfully

request that the present objection to claims 2-13, 39-40, and 42-52 be reconsidered and withdrawn.

Rejection under 35 U.S.C. § 112, second paragraph

Claim 19 was rejected under 35 U.S.C. § 112, second paragraph. The Examiner asserts that the "claim scope is uncertain since [a] trademark or trade name cannot be used properly to identify any particular material or product." Paper No. 5 at page 3. Applicants respectfully traverse.

Without acquiescing to the Examiner's rejection, and solely in order to promote the progress of the present application, Applicants have amended claim 19. The amendment to claim 19 deletes the phrase "L-Optizinc ZML-200 Inter-Health™" and replaces it with "zinc L-methionine," the active ingredient in the previously-recited product.

Applicants thus respectfully request that the rejection of claim 19 under 35 U.S.C. § 112, second paragraph, be reconsidered and withdrawn.

Rejection under 35 U.S.C. § 102(b)

Claims 1-13, 20, 23, and 25 were rejected under 35 U.S.C. § 102(b). Paper No. 5 at pages 3 and 4. Specifically, the Examiner asserts that Centrum® anticipates claims 1-13, 20, 23, and 25. *Id.* Applicants respectfully traverse.

To support an anticipation rejection under 35 U.S.C. §102, the Examiner must demonstrate that each and every element of a claimed invention is disclosed within a single prior art reference. *In re Bond*, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir. 1990). In other words, to anticipate the claim must encompass and empower a patentee or assignee to exclude others from making, using, or selling a product described in said printed publication. *Helifix Ltd. v. Blok-Lok Ltd.*, 54 U.S.P.Q.2d 1299, 1304 (Fed. Cir. 2000). Indeed, the printed publication must describe an applicant's claimed invention sufficiently to have placed a person of ordinary skill in the art in the field of the invention in possession of it. *See generally In re Paulson,* 31 U.S.P.Q.2d 1671 (Fed. Cir. 1994).

Amended independent claim 1 recites a composition for supplementing nutritional deficiencies in a patient or person in need thereof, comprising about 45 mg to about 55 mg vitamin C, about 31.5 IU to about 38.5 IU vitamin E, about 180 µg to about 220 µg chromium, about 63 µg to about 77 µg selenium, about 18 mg to about 22 mg zinc, and B-complex.

Centrum® discloses a composition comprising vitamin C, vitamin E, chromium, Selenium, Zinc, and B-complex (20 mg of niacin, vitamin B6 or pyroxidine, thiamine, riboflavin, vitamin B12 or cyanocobalamin, 10 mg of pantothenic acid, folic acid, and biotin).

Centrum® fails to disclose each and every element of amended independent claim 1. Indeed, this prior art reference does not place one of ordinary skill in the art in the possession of the claimed composition of independent claim 1. Specifically, Centrum® fails to disclose the particular ranges of the components of the compositions of amended independent claim 1, specifically, about 45 mg to about 55 mg vitamin C, about 31.5 IU to about 38.5 IU vitamin E, about 180 µg to about 220 µg chromium, about 63 µg to about 77 µg selenium, and about 18 mg to about 22 mg zinc.

For this reason, Applicants respectfully request that the present rejection of claims 1-13, 20, 23, and 25 under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

Rejection under 35 U.S.C. § 103(a)

Claims 14-19, 21-22, 24, and 26-52 were rejected under 35 U.S.C. § 103(a). Paper No. 5 at pages 4-6. Specifically, the Examiner asserts that claims 14-19, 21-22, 24, and 26-52 are "unpatentable over Centrum in view of GNC Ultra Mega Green." *Id.* at page 4. Applicants respectfully traverse.

To maintain a proper rejection under 35 U.S.C. § 103, the USPTO must meet four conditions. First, the USPTO must show that the prior art suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. Second, the USPTO must show that the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in an applicant's disclosure. Third, the prior art must teach or suggest all the claim limitations. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Fourth, if an obviousness rejection is based on some combination of prior art references, the USPTO must show the teaching or motivation to combine the prior art references. *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). An obviousness rejection based on a combination of references and absent a specific hint or suggestion necessarily comprises the use of hindsight long proscribed by Federal Circuit precedent. *See, e.g., In re Dembiczak*, 50 U.S.P.Q.2d at 1617.

Amended independent claim 1 (upon which claims 14-19, 21-22, 24, 26-30, and 36 depend) claims a composition for supplementing nutritional deficiencies in a patient or

person in need thereof, comprising about 45 mg to 55 mg vitamin C, 31.5 IU to 38.5 IU vitamin E, about 180 µg to about 220 µg chromium, about 63 µg to about 77 µg selenium, about 18 mg to about 22 mg zinc, and B-complex.

Independent claim 37 (upon which claims 38-52 depend) defines a composition for supplementing nutritional deficiencies in a patient or person in need thereof, comprising about 45 mg to about 55 mg vitamin C, about 31.5 IU to about 38.5 IU vitamin E, about 2.25 mg to about 2.75 mg folic acid, about 270 µg to about 330 µg biotin, about 9 mg to about 11 mg pantothenic acid, about 180 µg to about 220 µg chromium, about 63 µg to about 77 µg selenium, about 18 mg to about 22 mg zinc, about 18 mg to about 22 mg niacin, about 13.5 mg to about 16.5 mg pyridoxine, about 1.8 mg to about 2.25 mg riboflavin, about 10.8 µg to about 13.2 µg cyanocobalamin, and about 2.7 mg to about 3.3 mg thiamine.

The Examiner acknowledges that "Centrum does not teach the particular forms of Vitamin C, E, and B-complex, neither does it teach the particular salt of Chromium, Selenium, and Zinc." *Id.* at page 5. Further, the Examiner acknowledges that "Centrum does not teach the particular amounts of vitamin B6, or pyroxidine, thiamine, riboflavin, vitamin B12 or Cyanocobalamin, folic acid, biotin, selenium, zinc and chromium herein." *Id.*

Thus, the primary reference is deficient to support the present rejections. Specifically, Centrum® fails to teach or suggest the ranges of the components of both amended independent claim 1 and independent claim 37. For example, Centrum® fails to teach or suggest compositions comprising about 45 mg to about 55 mg vitamin C, about 31.5 IU to about 38.5 IU vitamin E, about 180 µg to about 220 µg chromium, about 63 µg to about 77 µg selenium, and about 18 mg to about 22 mg zinc.

GNC Ultra Mega® Green fails to remedy these deficiencies of the primary reference. Specifically, like Centrum®, GNC Ultra Mega® Green fails to teach or suggest the ranges of the components of both independent claim 1 and independent claim 37. For example, GNC Ultra Mega® Green fails to teach or suggest compositions comprising about 45 mg to about 55 mg vitamin C, about 31.5 IU to about 38.5 IU vitamin E, about 180 µg to about 220 µg chromium, about 63 µg to about 77 µg selenium, and about 18 mg to about 22 mg zinc.

Moreover, the Examiner has not shown the teaching or motivation to combine Centrum® and GNC Ultra Mega® Green to produce either of the compositions of amended independent claim 1 or independent claim 37. Indeed, GNC Ultra Mega® Green sets forth no teaching or suggestion that its teaching should be combined with the teaching of Centrum®.

Applicants' invention is directed to a composition comprising optimized amounts of vitamins and minerals within the claimed ranges. These elements are neither taught nor suggested by Centrum® or GNC Ultra Mega® Green, alone or in combination. Indeed, the Examiner's contentions that "[i]t would have also been obvious to one of ordinary skill in the art to optimize the amounts of each of these vitamins and minerals" and that "[o]ptimization of amounts is within the skill of the artisan and is therefore obvious" have no support and, more significantly, do not address Applicants' claimed ranges. *Id.* at pages 5 and 6. Similarly, the Examiner's contentions that "[e]mploying a known salt, acid, ester of a known compound in lieu of the compound itself is within the skill of the artisan" and that "the Skilled Artisan would expect the salt, acid, ester of a known compound to exhibit therapeutic effects similar to those of the compound itself" have no support. *Id.* at page 6. If the Examiner maintains these contentions, however, Applicants respectfully request the Examiner to specifically address the claimed ranges and to support these contentions with an affidavit or with references, in satisfaction of MPEP 706.02(j).

optimized is w/i the skill of the artisan

Accordingly, the claimed compositions would not have been obvious in view of the prior art and Applicants respectfully request that the present rejection of claims 14-19, 21-22, 24, 26-52 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

CONCLUSION

For the foregoing reasons, Applicants submit that all of the claims are in condition for allowance. The Applicants respectfully request entry of the amendments and reconsideration and withdrawal of the pending rejections. Should there by any further matters requiring consideration, the Examiner is invited to contact the undersigned counsel.

If there are any further fees due in connection with the filing of the present reply, please charge the fees to undersigned's Deposit Account No. 50-1067. If a fee is required for an extension of time not accounted for, such an extension is requested and the fee should also be charged to undersigned's deposit account.

Respectfully submitted,

29 May 2002

Don J. Pelton
Reg. No. 33,754

McKenna & Cuneo LLP
1900 K Street NW
Washington, D.C. 20006-1108
Telephone: 202.496.7500
Facsimile: 202.496.7756

Specification Amendments, 29 May 2002

Page 13, line 16 (amended)

L-Optizinc ZML-200 Inter-Health (zinc L-methionine) 20 mg

Claim Amendments, 29 May 2002

1. (amended) A composition for supplementing nutritional deficiencies in a patient or person in need thereof, comprising about 45 mg to 55 mg vitamin C, about 31.5 IU to about 38.5 IU vitamin E, about 180 µg to about 220 µg chromium, about 63 µg to about 77 µg selenium, about 18 mg to about 22 mg zinc, and B-complex, wherein said composition is administerable to a patient or person.

19. (amended) The composition of claim 1, wherein said zinc comprises zinc L-methionine [L-Optizinc ZML-200 Inter-Health™].

36. (amended) The composition of claim 1, wherein said vitamin E comprises d-alpha tocopheryl succinate [is] in the range of about 31.5 IU to about 38.5 IU.

37. (amended) A composition for supplementing nutritional deficiencies in a patient or person in need thereof, comprising about 45 mg to about 55 mg vitamin C, about 31.5 IU to about 38.5 IU vitamin E, about 2.25 mg to about 2.75 mg folic acid, about 270 µg to about 330 µg biotin, about 9 mg to about 11 mg pantothenic acid, about 180 µg to about 220 µg chromiumv, about 63 µg to about 77 µg selenium, about 18 mg to about 22 mg zinc, about 18 mg to about 22 mg niacin, about 13.5 mg to about 16.5 mg pyridoxine, about 1.8 mg to about 2.25 mg riboflavin, about 10.8 µg to about 13.2 µg cyanocobalamin, and about 2.7 mg to about 3.3 mg thiamine, wherein said composition is administerable to a patient or person.